Assistant Commissioner
for Patents
Washington, D.C. 20231

TRAVERSAL AND REQUEST FOR RECONSIDERATION OF RESTRICTION AND ELECTION REQUIREMENTS UNDER 35 U.S.C. §121

Dear Sir:

In response to the Official Action dated February 15, 2002, applicants, by their undersigned attorneys, respectfully traverse and request reconsideration of the restriction and election requirements under 35 U.S.C. §121 in the above-identified patent application in light of the following remarks.

REMARKS

At the outset, it is noted that a shortened statutory period of one (1) month was set forth in the February 15, 2002 Official Action. The initial due date for response, therefore, was March 15, 2002. A petition for a one (1) month extension of the response period is presented with this response, which is being filed within the one (1) month extension period.

The February 15, 2002 Official Action requires restriction between seventeen (17) allegedly distinct groups of claims, as follows:

Group I: claims 42-53 and 80, drawn to polypeptides;

Group II: claims 56-60, 81-84, drawn to antibodies;

Group III: claims 61 and 62, drawn to a cell

culture;

Group IV: claim 63, drawn to nucleic acids encoding antibodies;

Group V: claim 68, drawn to a method of making an antibody;

Group VI: claims 54 and 55, drawn to a fusion protein;

Group VII: claim 69, drawn to peptide vaccine;

Group VIII: claims 70, 89 and 90, drawn to a method of making a vaccine;

Group IX: claims 64-67, 71, 75-76 and 95, drawn to nucleic acids encoding peptides;

Group X: claims 85-86, 91, 93-94 and 96, drawn to nucleic acids encoding fusion peptides;

Group XI: claim 92, drawn to a method of making a fusion peptide;

Group XII: claim 88, drawn to a nucleic acid vaccine;

Group XIII: claims 77-78, 97 and 99, drawn to methods of treatment with a peptide;

Group XIV claims 79, 98, 100-101, drawn to gene therapy;

Group XV: claims 72-73, drawn to a method of making a peptide;

Group XVI: claim 74, drawn to a method of making

a peptide; and

Group XVII: claim 87, drawn to a fusion protein vaccine.

Applicants respectfully submit that the above restriction requirement is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty (PCT). As stated in § 1893.03(d) of the M.P.E.P.:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications...
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept. A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior

> art... Note also examples 1-17 of Annex B part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P.

The present invention is directed to isolated peptide fragments having at least one MHC-binding epitope of Tek protein, which peptide fragment is substantially free of sequences that are not part of the aforesaid binding epitope of Tek and which is capable of stimulating an immune response. Nucleic acid sequences encoding the peptide fragment of the invention, vectors and other constructs comprising such nucleic acid sequences, antibodies and antibody fragments directed against such peptide fragments, fusion proteins comprising the peptide fragments, pharmaceutical compositions comprising the peptide fragments and methods of use thereof are additional aspects of the present invention. Notwithstanding that there are a number of different aspects of the present invention, however, they all have as a common technical feature the above-mentioned peptide fragments. As such, the PCT's unity of invention requirement is satisfied in the present case. Thus, Applicants respectfully submit that all of the pending claims have unity of invention, because they share a special technical feature that is characteristic of all aspects of the invention.

Applicants take exception to the assertion in the Official Action that the special technical feature that unifies the present invention is anticipated or rendered obvious by the prior art for the reasons stated in the International Preliminary

Examination Report. The Examiner's position in this regard does not take into account the fact that amendments have been presented upon entry into the U.S. national phase which are believed to overcome the objections set forth in the International Preliminary Examination Report. Consequently, the Examiner's reliance on the prior art cited in the International Preliminary Examination Report is misplaced. Furthermore, a general disclosure relating to polyclonal antiserum to Tek does not anticipate claims to a specific anti-body capable of specifically binding the peptide of the invention. Accordingly, applicants' antibody claims are not unpatentable in view of the prior art as the Examiner alleges. Accordingly, Applicants respectfully submit that the special technical feature that imparts unity of invention in this case, namely, the aforementioned peptide fragments, have not been disclosed or suggested by the prior art.

Moreover, in M.P.E.P. §1850, subsection C, it is stated that:

> The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
> (A) In addition to an independent claim for **a given product**, an independent claim for **a process specially adapted for the manufacture of the said product**, and an independent claim for **a use of the said product**;... *[emphasis added]*.

This provision is directly applicable to the present claims which are directed to the nucleic acid products of claims 64-67, 71, 75, 76 and 95 (Group IX), the methods of making such products, as claimed in claims 72 and 73 (Group XV) and the method of using the nucleic acids to make a pharmaceutical, as claimed in claim 90 (Group VIII, in part). In light of this M.P.E.P. provision, unity of invention clearly exists between Groups VIII, in part, IX and XV.

Further, the above-referenced PCT Administrative Instructions quite clearly state that unity of invention exists between a protein and the DNA sequence encoding the protein. *See* Example 17. Unity of invention, therefore, also exists in the present case between Groups I and IX.

In sum, Applicants respectfully submit that all the pending claims of the present application possess unity of invention. In this regard, it is noteworthy that during the international stage of this application, the subject matter of all of the claims then pending herein, i.e., claims 1-38, was treated as one inventive concept, as can be seen from the aforementioned International Preliminary Examination Report.

At the very least, the claims of Groups I, VIII, IX and XV should be examined together in this application, based on the above-cited authorities. It is noted in passing that in the event the claims of Group I are examined in this application, claims 70 and 89 of Group VIII should be examined as well, in view of the clear relationship between the subject matter of

these two (2) sets of claims.

Plainly, for the foregoing reasons, the restriction and election requirements in this case fail to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. Accordingly, Applicants respectfully request that the restriction and election requirements be withdrawn upon reconsideration, and that all the pending claims be examined together in this application.

In order to be fully responsive to the above-mentioned requirement, however, Applicants hereby provisionally elect the subject matter of Group IX, that is, claims 64-67, 71, 75, 76 and 95 for consideration in this application.

Applicants further elect the species represented by peptide Z32. Claims 42, 44-51, 64-67, 69-80, 88, 90, 95, 98 and 100 are readable on the elected species and should be examined therewith.

These elections are made with traverse, for the reasons discussed above.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, directed to the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully requested.

Respectfully submitted,

Patrick J. Hagan
Reg. No. 27,643
Attorney for Applicant

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